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Pharma News

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**Mallinckrodt
Pharmaceuticals**

Addiction Treatment / A Collaborative Effort

ADDICTION TREATMENT REACHES OUT TO MOSCOW

On March 30-31, Mallinckrodt Pharmaceuticals sent a delegation to Moscow to attend "The Health of the Nation and the Fight Against Narcoterrorism" conference sponsored by the League of Health of a Nation. Vince Kaiman, Vice President and General Manager of Mallinckrodt Pharmaceuticals, Bob Lesnak, Director of Sales and Marketing for Addiction Treatment, Mike Neely, Director of Marketing for Addiction Treatment, and Annett Brown, Market Research Analyst for International, took part in the two-day event to discuss the problem of narcotic addiction in Russia and ways of dealing with it. Medication assisted treatment programs such as those practiced in the United States and elsewhere in the world, with medicines such as Methadone, are illegal and are unavailable in Russia.

Currently, Russia is battling a growing problem with heroin addiction. This epidemic is contributing to the death rate due to the rise in HIV/AIDS infection, 90 percent of which is spread through the use of shared hypodermic needles. The drug crisis is also of particular concern to the Russian government as a source of




Bob Lesnak, Annett Brown, Mike Neely, Dr. Mercedes Lovrecic (International presenter from Slovenia), Vince Kaiman, and Gene Haislip (Consultant)

support to terrorism - the majority of the heroin coming into the country originates in Afghanistan. Given the health and security issues raised by this national problem, the Russian government recognizes the need for a solution.

Mallinckrodt Pharmaceuticals and Russian consultants have been discussing the use of methadone in treating heroin addiction for the past two years. These discussions were presented at the conference in March as one possible solution to the addiction problem the country currently faces.

The Russian government does have some concerns. Of major concern is the infrastructure required to support the program.

The support of a national heroin addiction program raises issues with cost and security. The government may not be able to afford the methadone treatment program modeled by the United States. However, Russia may decide to develop their own program based on their financial capabilities and customize the program to fit their cultural needs.

The March conference resulted in the attendees signing a resolution that recommends establishing a committee in the League of Health of a Nation and also within the Ministry of Health to evaluate the possibilities of developing and implementing a medication assisted treatment program for heroin addiction. This is a major breakthrough in the policy orientation of the Russian government. A likely next step will be to request a trial of a treatment program. There is also the possibility of a meeting with practitioners in the United States to demonstrate the methadone treatment system here. Mallinckrodt Pharmaceuticals will continue to provide expert advice and support throughout the study and implementation of methadone treatment in Russia. 



Vince Kaiman,
Vice President and
General Manager
of Mallinckrodt
Pharmaceuticals

MESSAGE FROM VINCE

Every day, we park our cars in the parking lot, walk into the building,

and get ready for the task at hand. We go through our day maintaining our focus on the jobs we must complete

before we walk back out to the parking lot, get into our cars, and drive away. In the security of this work routine, it is easy for us to lose focus on the reason we are here in the first place - to provide a service to our customers.

Who are these customers? We have many customers we serve on a daily basis - wholesalers, community pharmacies, hospitals, physicians - but our ultimate customer is the patient at the end of the supply line who buys and consumes our product. This customer is the boss who drives our business forward. This is the boss we should all strive to please.

We do not operate in this market alone, and there will always be suitable alternatives to the products we offer. The area we must focus on to distinguish our company from our competitors is service, including everything from manufacturing a quality product to maintaining exceptional service to our customers. A high standard of service to the customer is what drives us forward in competition. Without this standard, the customer will turn to someone else.

While our ultimate customer is the patient, we must also not forget the supply chain that carries the product to that patient. When we neglect the customers within that supply chain, we create disruptions that affect the patient. These disruptions are reflections of our commitment to service, the one point we rely on to entice the customer.

How do we maintain our focus on the customer? Why is our goal of setting the highest standard in service so important? We must remember the nature of our business. The products we provide treat serious problems - pain, addiction, depression, and sleep-deprivation. We provide our customers with the means of regaining control of their lives. When we provide poor service, the effects on the patient are severe and do not go unnoticed. Therefore, we must constantly re-evaluate the business. We must always ask ourselves, "Are we doing the best we can for the customer?"

LETTER FROM THE EDITOR

Welcome to the premier edition of **PharmaNews**, the new communication vehicle devoted entirely to the Pharmaceuticals Dosage division of Mallinckrodt Pharmaceuticals. This quarterly newsletter is one avenue we are excited to utilize in an effort to enhance communication throughout our business. As this publication is meant to be a resource for you about the business for which you work and the people involved in that business, we welcome and encourage your feedback. If you have any questions or comments, or if you would like to submit an idea for a possible story in a future issue, please feel free to contact us at kellye.makamson@tycohealthcare.com.

We hope you enjoy this publication, and we look forward to providing you with the news affecting the work we do everyday.

EVEN ST. LOUIS CARDINALS' MASCOT FREDBIRD PITCHES MALLINCKRODT PHARMACEUTICALS PRODUCTS



Fredbird poses with Methadone and Hydrocodone Unit Dose packaging samples at the VHA Leadership Conference in St. Louis on May 22.

A SMALL BUSINESS WITH BIG ADS



Mallinckrodt Pharmaceuticals Outsourcing is supported by a large organization, but the business only has a total of seven employees, two of them within Marketing and Sales. In addition, they face stiff competition from companies that specialize in contract manufacturing with large budgets for marketing and advertising.

This does not stop Mallinckrodt Pharmaceuticals Outsourcing from creating attention-getting, believable ads. Since their new identity campaign launched in 2002, they have consistently ranked high in ad readership studies provided by the magazines.

Most recently, the trade magazine Pharmaceutical Technology

conducted their readership study, and here are some of their results:

- Mallinckrodt Pharmaceuticals Outsourcing outsourced ALL ads regarding attention-getting. The ad performed 13 percent higher in Attention-Getting Ability, Believability and Information Value than the average issue.
- Mallinckrodt Pharmaceuticals Outsourcing received one of the highest scores in Contract Services, only behind Cardinal Health by 1 percent. Seventy two percent of readers rated the ad as good or excellent for quality perception of the product/service.
- 46percent of readers said they took or plan to take one or more

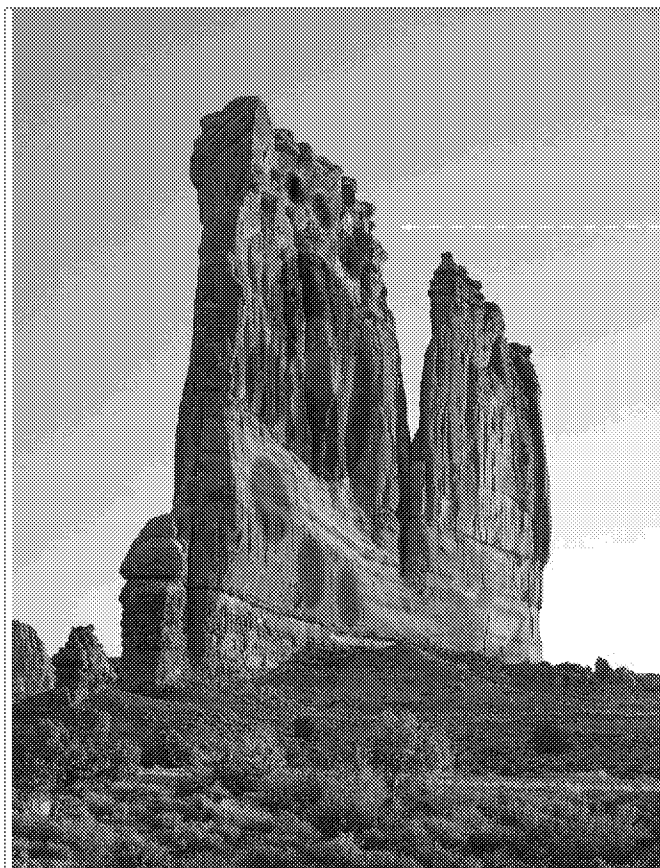
actions (visit site, contact, etc.).

Mallinckrodt Pharmaceuticals Outsourcing outsourced all ads in this question.

Mallinckrodt Pharmaceuticals Outsourcing has also won awards from the magazine Contract Pharma for "Outstanding Readership Response, As Measured Against All Other Ads Appearing in Contract Pharma" in 2002, 2003, 2004, and 2005.

An award from Pharmaceutical Technology is worded similarly: "In recognition of advertising which achieved outstanding readership response as measured against all other ads appearing in **Pharmaceutical Technology.**"

This award was given in May 2004.

A contract manufacturing relationship that stands the test of time.

With Mallinckrodt Pharmaceuticals Outsourcing, you'll find a rock solid partner that provides quality solid dose and oral liquid finished products. Our exceptional customer service, which defines Mallinckrodt, ensures that your project will receive the high level of attention it deserves.

Our goal is to form long-term strategic partnerships, focused on providing responsive service to manufacture your products on time and within budget. Mallinckrodt Pharmaceuticals Outsourcing draws on the knowledge and experience of over 3,500 professionals, whose skills span from product development and manufacturing solutions, all the way through to product launch. And when coupled with the financial resources of Tyco International, you'll have a strong partner to grow with.

Our philosophy is simple. Find a strategic partner that's a natural fit -- then provide them with lasting results. For a comprehensive list of our services and capabilities, please visit our website or call Melissa (807) 595-0709.

From development to commercial product launch, we offer the following services:

- Mallinckrodt API
- Process Development
- Clinical Supplies Manufacturing
- Analytical Development and Validation
- QA/QC Stability Testing Programs
- Process Scale Up & Validation
- Regulatory Consultation/Submission (IND, NDA, ANDA)
- Commercial Manufacturing and Packaging
- Unit Dose Blister Packaging with Bar Coding

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www.pharmaceuticals.mallinckrodt.com/outourcing

tyco
Healthcare

A contract manufacturing relationship that stands the test of time emphasizes to customers that with Mallinckrodt they will find a rock solid partner that provides quality products and services.

GENERICS INSIDE SALES EXCEEDS EXPECTATIONS IN FACE OF GREAT CHALLENGES




The Generics Inside Sales team successfully finished Second Quarter while facing several obstacles. They anticipated the approval of the Fentanyl Patch, and those expected sales were included in the budget. However, the product is still not approved. In addition to the absence of Fentanyl product, they had no new products during that time, and they were dealing with backorders around \$30M.

In spite of the many negative factors working against them, all five Inside Sales Representatives met or



Kathy Westbrook

exceeded their Sales Budget for the Second Quarter. The group as a whole came in 7 percent over budget, meaning they made 7 percent more than they anticipated. "With the backorder situation and the lack of new product, this is quite an accomplishment," says Kathy Westbrook, Inside Sales Manager. 



MALLINCKRODT PHARMACEUTICALS ACCEPTS AWARD

Mallinckrodt Pharmaceuticals was chosen as the recipient of the 2006 American Society of Consultant Pharmacists (ASCP) Foundation Industry Partner of the Year Award for our work with ASCP on several common projects. This

is the second consecutive year that Mallinckrodt has been chosen for this award. Steve Mullenix, Manager of Business

Relations, accepted the award on behalf of Mallinckrodt at a special award reception held at the Paris Hotel on April 22 during the 2006 ASCP Mid-Year Clinical Conference. Mallinckrodt Pharmaceuticals was also recognized as a sponsor of this Leadership Reception. During the evening, Bob Miller, President of ASCP, toasted "Mallinckrodt's demonstrated commitment to the ASCP Foundation, ASCP, its members, and the patients we serve," expressing sincere appreciation for Mallinckrodt's support. 

HOBART COMPLETES SUCCESSFUL INSPECTION

On February 27, 2006, the FDA visited Mallinckrodt Pharmaceuticals' Hobart Manufacturing facility for a 12 day General Inspection. This is the first visit since an inspection in June 2005 identified deficiencies, and this time the facility demonstrated remarkable improvement as a quality pharmaceutical manufacturer. The plant was found "compliant in all respects," an "extraordinary achievement that could not have happened without the commitment of our outstanding workforce," says Jay Sawardeker, Vice President of Quality Assurance and Regulatory Affairs.

When asked how the plant was able to turn its performance around in such a short time, Chuck Kruger, Human Resources Manager at Hobart, explained that everyone involved has been working hard to make changes. Also, the employees followed three key learning points: doing it right the first time, working on the principle of "Quality Matters," and emphasizing prevention.

These key learning points are the result of an ongoing process called Change Management instilled since the previous inspection. Change Management is a project involving every employee from Quality and Production and

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FDA CHANGES LABEL REGULATIONS

Every year, more than 2 million people in the United States suffer from an adverse drug reaction, or ADR (FDA). These reactions result in over 100,000 deaths annually, making ADRs the fourth leading cause of death in the nation, ahead of such other major causes as pulmonary disease, diabetes, and automobile accidents (FDA). In addition to physical consequences, ADRs can also dramatically affect the cost of healthcare. The FDA reports that the "mean length of stay, cost and mortality for ADR patients are DOUBLE that for" patients with no adverse reaction. This problem produces an estimated cost of \$136 billion annually.

Recognizing the significant costs, physical - financial, to the patient who experiences an ADR,

the FDA in January released new regulations for prescription drug labeling, the first major revisions in over 25 years. The new regulations, called the Physician's Labeling Rule (PLR), are intended to simplify the information available to physicians, pharmacists and patients on the package insert (PI) included in the packaging of all drugs. The new format of the PI is intended to make it easier for physicians and pharmacists to quickly locate the most important information about a drug, including any major risks associated with the product, and to communicate this information to the patient. The revisions should also make the language of the PI more accessible to the patient, moving from a strictly clinical approach to one easily


understood by those not in the medical field.

The revised format divides the package insert into three primary sections: (1) Highlights of Prescribing Information; (2) Full Prescribing Information; Contents; and (3) Full Prescribing Information.

Additional changes include adding the date of initial product approval, listing a toll-free number and Internet site for reporting adverse events, and increasing the size of the print.

According to the FDA, "These revisions should enhance the safe and effective use of prescription drug products and in turn reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly

applied drug information." A decrease in ADRs, in addition to better quality of life for the patient, also means a potential reduction in the cost of healthcare.

The regulations are scheduled to go into effect on June 30, 2006, and apply to all prescription drugs approved since June 30, 2001. Changes on products approved before that date are voluntary. Mallinckrodt Pharmaceuticals is currently reviewing the necessary steps for complying with the new regulations. Employees can expect to see a gradual implementation of the new PI regulations over the next few years. We will keep you informed of the progress as the changes are made. 

HOBART

(continued from page 4)

other disciplines working together under five pillars within the company to correct the root cause of all underlying problems.

Through Change Management, the employees at Hobart are able to have faith in the process used to correct the problems the plant faces. Change Management covers many areas, including material handling, physical plant, and organizational structure. The project is expected to last until the plant achieves "World Class Status." 



Mallinckrodt Pharmaceuticals' Hobart Facility is found "compliant in all respects" during its recent FDA inspection following the newly implemented Change Management program.



PHARMACEUTICALS EDUCATES CUSTOMERS

Mallinckrodt Pharmaceuticals is widely known for providing high quality pharmaceutical products. The company was built on a dependable reputation based on the quality of its products, a standard set by the Mallinckrodt brothers more than a century ago. In addition to quality of product, the company is also recognized for its commitment to service, and today, Pharmaceuticals offers an important service to some of its customers through various Continuing Education (CE) programs.

Currently, Brands, Generics, and Addiction Treatment all offer a CE credit program through Mallinckrodt Pharmaceuticals. These programs are designed to provide people with information about the health issues treated by Mallinckrodt products. While some of the programs have been in place for up to a year, others launched as recently as last month.

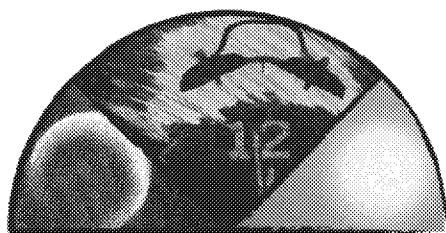


Illustration courtesy of *Pharmacy Times*

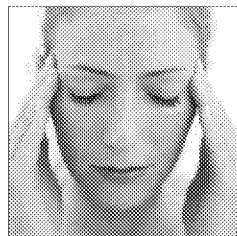
Brands offers help with treating insomnia patients.

"A Good Night's Rest - Helping the Patient with Insomnia" appears in the May issue of *"Pharmacy Times"* with an option to complete the course online. For the next three years, at which time the course will expire, pharmacists may earn two contact hours (worth 0.2 Continuing Education Units) toward their annual

requirements for continuing education.

"We recently began calling on pharmacies again, and we wanted to offer [pharmacists] a value-added service," says Mike Wessler, Product Manager for Brands.

Generics also offers a CE course entitled, "Pharmacist Pain Management: A Focus on Opioids and Conversion Issues." Like the course offered by Brands, this program



Nearly 3000 pharmacists have already completed the Generics pain management program.

also is worth two contact hours toward the required CEUs for pharmacists each year. Since its inception in May 2005, nearly 3,000 pharmacists have completed the course.

According to John Adams, Senior Product Manager for Generics, "During a previous survey, pain management was one category in which pharmacists expressed an interest in learning additional information. As a leader in pain management, it was reasonable for us to answer that interest."

While the current program will still be available for an additional two years, Generics hopes to offer other courses before that expiration date.

The Addiction Treatment CE program differs significantly from those offered by Brands and Generics in that it consists of training classes actually instructed by National Account Managers (NAMs).

Introducing...

Mallinckrodt MMTP
Methadone Training Program
Sponsored by Mallinckrodt



CEU Credits Now Available

Addiction Treatment has developed seven different training programs offered to counselors, medical personnel and patients.

The business offers seven different modules for credit: "History and Medical Basis of Methadone in the Treatment of Opioid Addiction;" "Achieving Adequate Methadone Dosage in the Treatment of Opioid Addiction;" "Using Methadone Safely in the Treatment of Opioid Addiction;" "Understanding Addiction;" "A Disease Perspective of the Addicted Brain;" "Dual Disorders: Addiction Plus Mental Illness;" and "Substance Abuse Monitoring;" Each of these seven courses is worth two contact hours.

Although Addiction Treatment has been offering this training to clinic counselors, medical staff, and patients for two years, this is the first year that the classes will be worth CE credit. Methadone clinics are evaluated and certified based on these CE credits. "People began asking us why we're not offering CE credit," says Bob Lesnak, Director of Sales and Marketing for Addiction Treatment. So the business began exploring possible credentialing institutions, eventually settling on National Association of Alcoholism and Drug Abuse Counselors (NAADAC) because it covers the bulk of the 50 states. The program will expire every two years but can be renewed for a fee.

PRODUCT UPDATE

New products:

Hydromorphone Hydrochloride Tablets (8mg, 100ct.), Metformin, Methadone Hydrochloride Tablets (5 and 10mg, 100UD), Morphine Sulfate ER (15 and 30mg, 100UD), Promethazine (12.5, 25, and 50mg), Ribavirin Tablets and Capsules (200mg), Warfarin Sodium Tablets (1, 2, 2.5, 3, 4, 5, 6, 7.5, and 10mg)

Revised Pls:

Fluoxetine capsules and oral solution—new revision date 12/30/05

Oxycodone Hydrochloride Tablets (5mg, 100ct. and 100UD) - new revision date 05/02/05

Restoril - new revision date 4/21/06

Product Revisions:

Morphine Sulfate ER Tablets, 60mg (100UD) - revised shelf carton quantity and weight - March 2006

Oxy/APAP Tablets (7.5mg/500mg, 100ct.) - new shelf carton package dimensions and case quantity - January 2006

New medication guides: Anafranil, Fluoxetine capsules and oral solutions, Pamelor, Tofranil PM


Products discontinued:

Anexsia Tablets (5mg/500mg, 100ct.)

Anexsia Tablets (7.5mg/650mg, 100ct.)

Mixed Salts (5, 7.5, 10, 12.5, 15, 20, and 30mg, 100ct.)

Morphine Sulfate ER (15, 30, 60, and 100mg, 500ct.)

This list is for internal use only. It represents the product changes since January 2006 to the best of our knowledge. If you have any specific questions regarding these products, please contact the product manager. 

THC SEPARATION UPDATE

tyco / Healthcare

A separation management team has been formed to direct and oversee the work that has to be done over the next twelve months. Here is their progress report:

- Senior Advisory Board formed and meets bi-weekly
- Functional teams formed and preparing detailed project plans
- Finance and Legal organizations preparing to begin executing the internal transactions necessary to achieve the separation
- Finance, Legal and HR organizations within Electronics and Healthcare planning the activities necessary to operate as stand-alone companies

Communications Guidelines

Here are Tyco Healthcare's current communications guidelines:

Marketing Communications


- Maintain the current Branding/Visual Identity of Tyco
- Manage production/physical stock with the transition timing in mind
- Likely three new identities will debut on day of introduction of new companies - although we should receive more information mid-year

Internal Communications

- Maintain focus/messaging on business performance
- Separation communications can be found at Inside Tyco and Tyco World

External Communications

- Direct all corporate, separation-related and financial communications requests to corporate Media Relations

For more information, visit <https://inside.tyco.com>. 

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